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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,667	07/23/2004	Avi J. Ashkenazi	39780-2630 P1C1C1	9729

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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,667	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1 – 11 and 20, drawn to isolated nucleic acids, vectors, host cells, and methods of making protein, classified in class 435, subclass 69.1, for example.

   II. Claims 12 – 17 and 21, drawn to isolated proteins, classified in class 512, subclass 12, for example.

   III. Claims 18 – 19, drawn to antibodies, classified in class 424, subclass 130.1, for example.

   IV. Claims 22 – 37, drawn to methods of detecting protein comprising contacting a sample with a PRO polypeptide, classified in class 435, subclass 7.1, for example.

   V. Claims 38 – 49, drawn to methods of linking a bioactive molecule to a cell comprising contacting said cell with a PRO polypeptide that is bound to a bioactive molecule, classified in class 435, subclass 7.1, for example.

   VI. Claims 50 – 57, each in part, drawn to methods of modulating at least one biological activity comprising contacting a cell with a protein, classified in class 514, subclass 12, for example.

   VII. Claims 50 – 57, each in part, drawn to methods of modulating at least one biological activity comprising contacting a cell with an antibody, classified in class 424, subclass 130.1, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and III are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polynucleotide of Group I and the polypeptide of Group II are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of

Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. As such, it would be burdensome to search the inventions of Groups I and II.

The polypeptide of Group II and the antibody of Group III are patentably distinct for the following reasons: while the inventions of both Groups I and III are polypeptides, in this instance, the polypeptide of Group II is a single chain molecule, whereas the polypeptide of Group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of Group II and the antibody of Group III are structurally distinct molecules; any relationship between a polypeptide of Group II and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

In this case, the polypeptide of Group II is a large molecule which contains potentially hundreds of regions to which an antibody must bind, whereas the antibody of Group III is defined in terms of its binding specificity to a small structure within the disclosed SEQ ID NO. Thus, immunization with the polypeptide of Group II would result in the production of antibodies outside the scope of Group III. Therefore, the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of Group II and Group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and the antibody to which the polypeptide binds require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group III. Furthermore, antibodies which bind to an epitope of a polypeptide of Group II may be known even if a polypeptide of Group II is novel. In addition, the technical

literature search for the polypeptide of Group II and the antibody of Group III is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

The polynucleotide of Group I and the antibody of Group III are patentably distinct for the following reasons: the antibody of Group III includes, for example, IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibody of Group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group I will not encode an antibody of Group III, and an antibody of Group III cannot be encoded by a polynucleotide of Group I. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Groups I and III would impose a serious search burden since a search of the polynucleotide of Group I would not be used to determine the patentability of an antibody of Group III and vice-versa.

Invention I is not related to any of Inventions IV - VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to nucleic acid products (group I) and methods of using protein or (groups IV – VI) or antibodies (group VII). As set forth in the previous paragraphs, the products are patentably distinct and cannot be substituted one for the other. The nucleic acids of Group I cannot be used in any of the methods of Groups IV – VII. Consideration of the methods requires search for the methods of using different products which are not encompassed by the search required for consideration of Group I. Thus it would be burdensome for the examiner to consider any of Groups IV – VII with Group I.

Invention II is related to Inventions IV – VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product. See MPEP § 806.05(h). In the instant case the protein can be used in any of the three methods. Furthermore, consideration of each of the methods requires search for the particular method steps, which are not required for consideration of the protein itself. The methods of using the proteins may be novel or non-obvious even if the proteins are old. Thus it would be burdensome for the examiner to consider Group II with any of Groups IV – VI.

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibodies of Invention III can be used to purify the protein from a heterogeneous sample. Consideration of the methods requires search for the particular method steps, which are not required for consideration of the antibody itself. The methods of using the antibodies may be novel or non-obvious even if the products themselves are old. Thus it would be burdensome for the examiner to consider Groups III and VII together.

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to protein products (group II) and methods of using antibodies (group VII). As set forth above, the products are patentably distinct and cannot be substituted one for the other. The proteins of Group II cannot be used in any of the methods of Group VII. Consideration of the methods requires search for the methods of using different products which are not encompassed by the search required for consideration of Group II. Thus it would be burdensome for the examiner to consider Groups II and VII together.

Invention III is not related to any of Inventions IV – VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to antibody products (group III) and methods of using protein or (groups IV – VI). As set forth above, the products are patentably distinct and cannot be substituted one for the other. The antibodies of Group I cannot be used in any of the methods of Groups IV – VI. Consideration of the methods requires search for the methods of using different products which are not encompassed by the search required for consideration of Group

III. Thus it would be burdensome for the examiner to consider any of Groups IV – VI with Group III.

Inventions IV – VI are unrelated, each to the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions each are drawn to methods of using proteins, but require different starting materials and method steps, and they each have different goals. As such, they can support independent patent. Furthermore, searching for the steps of any one method would not be informative as to the novelty or non-obviousness of any other method. The searches required are divergent. Thus consideration of more than one of Groups IV – VI together would be burdensome for the examiner.

Requirement for Further Restriction Within All Groups

3. Each of the seven groups above encompasses multiple products, identified by SEQ ID NO:. Each nucleic acid, protein, or antibody product is an independent and distinct invention which has unique biochemical and physical properties. Each can support its own patent. Furthermore, consideration of any one sequence requires a search of the appropriate computer database. Any one set of sequence search results would not be informative as to the novelty or non-obviousness of any other sequence. There is no evidence that the sequences share a common core sequence which imparts a common utility. Therefore, in order to be completely responsive to this restriction requirement, applicant must elect a single sequence, identified by SEQ ID NO:, for prosecution on the merits.

Applicant is advised that a reply to this requirement must include an identification of the sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Applicant is advised that this is not an election of species but is an additional requirement for restriction.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02) and because the different

inventions encompass divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DK

Daniel E. Kolker, Ph.D.
December 19, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER